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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MULTIPLE ENERGY TECHNOLOGIES, LLC,

Plaintiff,

vs.

HOLOGENIX, LLC,

Defendant.

HOLOGENIX, LLC,

Counterclaimant,

vs.

MULTIPLE ENERGY TECHNOLOGIES, LLC,

Counter-Defendant.

Case No. 2-19-CV-01483

PLAINTIFF MULTIPLE ENERGY TECHNOLOGIES LLC'S REPLY IN FURTHER SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION

Filed Concurrently With:
(1) Supplemental Declaration of Shannon Vissman;
(2) Supplemental Declaration of Alberto Gutierrez;
(3) Supplemental Declaration of Thomas Maronick;
(4) Plaintiff's Response to Defendant's Evidentiary Objections.

Complaint Filed: February 28, 2019
Counterclaim Filed: April 12, 2019

Date: June 3, 2019
Time: 1:30 p.m.
Courtroom: 9A
U.S. District Judge Percy Anderson

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PRELIMINARY STATEMENT

Defendant Hologenix, LLC ("Hologenix" or "Defendant") opposes Plaintiff Multiple Energy Technologies, LLC's ("MET" or "Plaintiff") motion for a preliminary injunction by relying on a letter from the Food and Drug Administration ("FDA") that proves Plaintiff's case. In response to Hologenix's request for permission to make broad claims about four specific items woven with Hologenix's fibers known as Celliant—a performance tee, an elbow wrap, a pillow, and a pair of socks—the FDA said no because doing so could "incorrectly suggest that the subject devices have undergone premarket review."

Hologenix and its chief executive promptly ignored this warning and instead claimed that 1) the FDA had "approved" Celliant, 2) the FDA had made a determination about Celliant itself, rather than the specific submitted products, and 3) the FDA had made a determination about the benefits of ***any product*** containing Celliant. These claims were false.

Likely aware that it cannot prevail on the merits, Hologenix defends by claiming that MET has delayed in filing suit. But there was no unreasonable delay here and ample Ninth Circuit case law holds that parties investigating claims before litigating should not be punished. Hologenix next suggests that the scope of the injunction should be narrow, but MET's proposed language is specifically tailored to address the false and misleading statements Hologenix has made.

Put simply, issuance of the requested preliminary injunction is necessary to prevent the irreparable harm that MET continues to suffer as a result of Hologenix's false statements. The Motion should be granted.

ARGUMENT

I. MET Is Likely To Succeed On The Merits

A. The FDA Letter Shows That Hologenix's Statements Are False

Hologenix's declarations readily illustrate that it repeatedly sought permission to make medical claims about Celliant and that the FDA repeatedly

refused. In 2009 the FDA told Hologenix that it could not advance the claims that it made here. (ECF 32-8 ¶ 12). In 2011, Hologenix asked if it could claim that Celliant "increased blood flow and circulation." The FDA again said no, indicating that such claims would require pre-market review. (ECF 32-8 ¶ 14). In 2014, Hologenix asked the FDA to classify garments with Celliant as medical devices; the FDA again denied the request. (ECF 32-8 ¶¶ 18, 20).

In 2016, Hologenix changed tactics, desperately wanting something it could claim in the campaign that is the subject of this action. Hologenix asked the FDA if it could make "simple wellness claims" related to four items and submitted another, limited request to the agency. (ECF 32-8 ¶ 27). The FDA responded to this final request by citing its general wellness policy, under which the agency does not require pre-market review for products that "(1) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons." (ECF 24-11 at 2). The FDA also said that, because Hologenix's claims were limited to the "intended use" of the tee, wrap, socks, and pillow, Hologenix could claim that they were "medical devices as defined in section 201(h) of the Act." (ECF 32-10 ("FDA Letter")).[1]

Thus, after years of rejection, Hologenix was able only to get the FDA to agree that it would not seek enforcement actions against Hologenix if it made claims about the "intended use" of the four identified products. As Alberto Gutierrez, a former FDA Director, confirmed after reviewing the FDA letter, the FDA's determination relates solely to the ***intended*** use and offers no support for the underlying claims of effectiveness. (Supp. Gutierrez Decl., ¶ 12). The FDA emphasized that including a product under the wellness policy "does not establish that it has been shown to be safe and/or effective for its intended use." (ECF 24-11

[1] Under Section 201(h), the term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (3) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321 (h)(3).

at 2).

The FDA warned Hologenix not to make claims suggesting it had reviewed Celliant: "Please also note that your proposed claim, "The FDA has reviewed this product and determined it to be a medical device" may ***incorrectly suggest that the subject devices have undergone premarket review***." (FDA Letter at 2, emphasis added). The FDA concluded that only the four identified Celliant products fell under the wellness policy and Section 201(h) because "they ***are intended*** to affect the structure or function of the body of man by temporarily promoting increased local blood flow at the site of application in healthy individuals," not because they actually do so. (FDA Letter at 1, emphasis added). The agency emphasized "a response to a 513(g) request is not a classification decision for a product and does not constitute FDA clearance or approval." (FDA Letter at 2).

But Hologenix disregarded the FDA response and issued a press release claiming that "According to the FDA, Celliant products were ***determined*** to be medical devices ***because they temporarily promote increased local blood flow*** at the site of application in healthy individuals." (ECF 24-14, emphasis added). This is ***exactly*** what the FDA stated that Hologenix could ***not*** do. The FDA did not determine that ***any*** Celliant products temporarily promoted increased blood flow. The FDA warned against making claims that it had "reviewed this product." (FDA Letter at 2). The FDA said nothing about any product other than the four identified in the letter. Hologenix's initial press release and subsequent campaign stating that the FDA had "approved" any Celliant-containing product or had "determined" that Celliant increased blood flow were false. Then, as much as Hologenix tries to deny it, it engaged in a campaign, led by its CEO, to spread the lies that the FDA had "determined" so much more than it actually had.

B. <u>Mr. Casden Made The Literally False Claims Himself</u>

Hologenix admits that its claims that the FDA "approved" Celliant are

literally false. (ECF 19 ¶ 4; Answer) ("Defendant admits that the FDA has not 'approved' the Product.") Its CEO, Seth Casden, now swears that the company "never had, and does not now have, a marketing plan that describes the technology as 'FDA-Approved.'" (ECF 32-8 ¶ 37). Casden blames others—unnamed "employees" or "consultants"—whom he implies acted without company authority when they spread and promoted the purported FDA approval, including using "#FDAapproval" on Facebook and Twitter. *Id.* ¶ 38. Nonsense. ***Casden himself made these claims***, and when he did so, he ***referenced the social media campaign***.

In August 2017, Casden discussed "[t]he approval that we have now" in a *Huffington Post* article that made it clear that the "approval" Hologenix had received involved the FDA's pre-market approval process. (ECF 24-19) In the September/October 2017 issue of *Textile Insight*, in an article with the subheading "Perseverance Pays Off for Celliant with ***FDA Approval***," Casden stated "There's been an overwhelming positive response to ***the FDA approval***." (ECF 24-21, emphasis added). The one-page article contains the words "FDA Approval" no fewer than ***eight times***, twice directly quoting Casden and another referencing the social media hashtag. Not until MET filed this action did Hologenix take any action to begin to correct the misleading and false claims that it had made. Casden and Hologenix cannot escape their literally false campaign by deleting some of the more offensive tweets ***after this lawsuit was filed*** and pretending they were the work of misinformed underlings.

Nor does partially scrubbing social media pages render MET's claims moot. After all, "courts across jurisdictions have often found the voluntary cessation of infringing conduct insufficient to moot a preliminary injunction." *Cherokee Inc. v. Wilson Sporting Goods Co.*, 2015 WL 3930041, at *4 (C.D. Cal. June 25, 2015). Hologenix has not sought corrections from any of the media outlets that stated that Celliant had been approved by the FDA. Casden has not retracted his statements to the *Huffington Post* or to *Textile Insight*. Absent an injunction, there is nothing to

prevent Hologenix from reviving its false campaign or failing to retract lingering misstatements. Incredibly, its website still links to the *Huffington Post* article with the FDA approval language and more articles continue to appear. *See Sierra On-Line, Inc. v. Phoenix Software, Inc.*, 739 F.2d 1415, 1422 (9th Cir. 1984) (affirming injunction when defendant "voluntarily stopped" challenged conduct).

Casden's declaration, in which he denies under penalty of perjury responsibility for quotes he himself provided to major media outlets, only demonstrates the low regard in which Hologenix holds the truth, and shows how vital it is that this Court enjoin Hologenix to stop the spread of false statements and correct the damage done by those it has made. (ECF 32-8 ¶ 37).

C. Hologenix's Claims Are False By Necessary Implication

Hologenix is quite right to state that the FDA's determination "must be afforded deference." (ECF 32, at 15, *citing United Food and Commercial Workers v. NLRB*, 307 F. 3d 760 (9th Cir. 2002)). But the FDA's determination was extremely limited, and the agency warned against expanding it. Hologenix ignored that warning. The FDA wrote that its letter addressed "the regulatory requirements applicable to the Celliant ***performance tee, elbow wrap, pillow, and socks***." (FDA Letter at 1). Even to the extent that it permitted Hologenix to state that these products were medical devices under Section 201(h) because of their intended uses, it did not provide blanket permission for Hologenix to claim that ***any*** product containing ***any amount*** of Celliant, for example, sleepwear and sportswear made by Under Armour, bedsheets made by American Textile, and equine blankets made by Draper Therapies, is a medical device. But that is precisely what Hologenix has done.

From the time it issued the press release, Hologenix ignored the FDA's limits regarding the statements it could make and the products those statements applied to. Instead, it claimed that the FDA had determined that ***all*** products made with

Celliant were medical devices "***because they temporarily promote increased local blood flow.***" (ECF 24-14, emphasis added). The claims, which "must always be analyzed in [their] full context," differ so much from what FDA said as to be false by "necessary implication." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997).

Hologenix's CEO and its consultant state that the FDA relied on scientific studies Hologenix provided when it concluded that the Celliant-based devices "are intended to affect the structure or function of the body of man." (ECF 32-8 ¶ 30; ECF 32-11 ¶ 24; FDA Letter p. 2). But nowhere in the FDA's letter are these studies mentioned, and nowhere does the FDA claim that its conclusions are premised on anything other than the product's "intended use." (FDA Letter p. 2). MET's expert, Alberto Gutierrez, has now reviewed the FDA letter and states that it confirms his earlier conclusion that "the FDA has not made a determination about the underlying benefits of Celliant." (Supp. Gutierrez Decl. ¶ 12).

The FDA provided precise language to Hologenix, and a warning that Hologenix's preferred language could carry a false suggestion. Hologenix ignored the warning and made its false claims the centerpiece of its sophisticated campaign of deception.

D. <u>The Consumer Survey Shows Materiality</u>

Hologenix does not deny that consumers surveyed by Dr. Maronick believed that Celliant's website implied that the FDA had endorsed its claims, arguing only that Maronick should have surveyed manufacturers instead. But Dr. Maronick surveyed the statements on Hologenix's website, which are consumer-facing and designed to persuade consumers to buy products manufactured with Celliant. (Supp. Maronick Decl. ¶¶ 8–9). Hologenix's campaigns, including social media posts, its own website, and statements to the national media, are all aimed at end consumers. Surveying consumers who may buy products with Celliant in them was proper because such surveys must cover "that segment of the population whose

perceptions and state of mind are relevant to the issues in the case." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 123 (4th Cir. 2011), (*citing* J. Thomas McCarthy, 6 McCarthy on Trademarks and Unfair Competition § 32:159 (4th ed. 2003)).

Hologenix's authorities support MET. In *ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. App'x. 609 (9th Cir. 2016), the Ninth Circuit considered a survey consisting of "consumers of testosterone boosters." *Id. at* 613. ThermoLife does not sell to these consumers. ThermoLife holds patents over various amino acid nitrates which it ***sells to manufacturers of dietary supplements***.[2] As in *ThermoLife*, the relevant perceptions here are those of the end consumers who are potential customers of products made with Celliant.[3] *Kournikova v. General Media Communications Inc.,* 278 F. Supp. 2d 1111, 1125 (C.D. Cal. 2003), also cited by Hologenix, states that "[t]o be probative and meaningful, . . . surveys . . . must rely upon responses by *potential customers* of the products in question (citing *Dreyfus Fund, Inc. v. Royal Bank of Canada*, 525 F. Supp. 1108, 1116 (S.D.N.Y. 1981). *See also Kwan Software Eng'g, Inc. v. Foray Techs., LLC*, WL 572290, at *5 (N.D. Cal. Feb. 11, 2014) (noting that the proper universe for a Lanham Act survey consists of "people who would see the alleged misrepresentations . . . [and] those whose decision to purchase the product could be influenced").

Dr. Maronick surveyed those targeted by Hologenix's claims, which "describe benefits that a consumer will derive from buying products made with Celliant's performance-enhancing material." (Supplemental Declaration of Dr. Thomas Maronick, ¶ 6). Manufacturers who sell products containing Celliant rely on and repeat Hologenix's claims. For example, Under Armour states on its website

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[2] On its website, ThermoLife directs its message to those "interested in making a dietary supplement with nitrates in it." *See* www.thermolife.com.

[3] *ThermoLife* also notes that "objections as to . . . an unrepresentative sample 'go only to the weight, and not the admissibility, of the survey" (quoting *Southland Sod Farms*, 108 F.3d at 1143).

that "Products powered by Celliant have been determined by the FDA to increase localized circulation, leading to faster recovery."[4]

II. Plaintiff Is Likely to Suffer Irreparable Harm

Hologenix argues that MET will not suffer irreparable harm in the future by emphasizing the extent to which Hologenix has ***already*** harmed MET. Hologenix selectively quotes MET's CEO as saying "MET has no customers and has no current prospect of finding any," while leaving out the caveat "***so long as Hologenix's false and misleading claims continue***." (ECF 24-1 ¶ 18, emphasis added). If Hologenix is enjoined from making false and misleading statements, then MET indeed could land customers—the reason it cannot do so now is that prospective partners believe that MET's product is inferior because it has not been "approved" by the FDA. (Supp. Vissman Decl. ¶ 15). MET's consultant confirms that he cannot find customers because Hologenix's FDA-related claims suggest Celliant is a superior product. (Supp. Vissman Decl. ¶ 16). Dr. Vissman's "credible assertions" that MET will fail without an injunction "are sufficient to constitute irreparable harm." *See hiQ Labs, Inc. v. LinkedIn Corp.*, 273 F. Supp. 3d 1099, 1105 (N.D. Cal. 2017). Statements by business owners that without an injunction "they would suffer a substantial loss of business and perhaps even bankruptcy" are regularly found to support a finding that irreparable harm is likely. *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975); *see also Int'l Franchise Ass'n, Inc. v. City of Seattle*, 803 F.3d 389, 411 (9th Cir. 2015).

Hologenix next argues that MET should have brought this suit in 2017, before MET could even tell whether Hologenix's claims were true. At that time, MET was under contract with Under Armour and expected that long term contracts with both Under Armour and American Textile were imminent. It was not until July 2018, when Hologenix announced its partnership with Under Armour and

[4] *See https://www.underarmour.com/en-us/mens-athlete-recovery-sleepwear-short-sleeve-crew/pid1329520-492.*

American Textile terminated its agreement with MET, that MET felt the impact of Hologenix's deceit. (Supp. Vissman Decl. ¶ 10).

Immediately following Under Armour's announcement that it was working with Hologenix and American Textile's termination of its MET contract, MET filed two FOIA requests with the FDA to learn the truth; the FDA has still not responded. (ECF 31-1 at 14–16). During the months since July 2018 and ending with the filing of this suit, MET asked Under Armour questions that remain unanswered, and attempted to sell its products. And MET engaged counsel and consultants in an effort to evaluate its legal position. (Supp. Vissman Decl. ¶¶ 11–12). MET should not be punished for conducting a "cautious investigation." *Disney Enterprises, Inc. v. VidAngel, Inc.*, 869 F.3d 848, 866 (9th Cir. 2017). And although these six months were spent investigating and are therefore not a delay, delay is only "a factor to be considered" among others, and the Ninth Circuit "would be loath to withhold relief solely on that ground." *Lydo Enterprises, Inc. v. City of Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984). In *Gilder v. PGA Tour, Inc.*, 936 F. 2d 417, 423 (9th Cir. 1991), the Ninth Circuit affirmed an injunction in a case filed approximately one year after a PGA rule had changed. *See also Wetzel's Pretzels, LLC v. Johnson*, 797 F. Supp. 2d 1020, 1029 (C.D. Cal. 2011) Here, the overwhelming support of the other factors favors issuing an injunction whether or not the six-month investigation is considered a delay.

III. The Balance of Hardships Favors an Injunction

Hologenix argues that the balance of hardships weighs in its favor, but its argument is aimed simply at the scope of the proposed injunction. Claiming that correcting its false statements will result in a "loss of reputation and goodwill," Hologenix fails to grapple with the fact that any goodwill gained from making false claims is without merit and earned at the expense of MET's reputation. (ECF 32 at 22). Aside from deleting a few social media posts, Hologenix has taken no steps to correct the record, and pretends it is powerless to correct the reporting that refers to

Celliant as "the only company with FDA approval as an infrared wellness device," as recently as April, 2019. (ECF 24-31). Without an injunction, Hologenix is likely to keep making false statements, continuing to harm MET. The balance of hardships does not favor a party that hopes to keep making false statements—rather, "there is no harm to a defendant from an injunction which prevents continuing dissemination of false statements." *POM Wonderful LLC v. Purely Juice, Inc.*, 2008 WL 4222045, at *16 (C.D. Cal. July 17, 2008) *aff'd*, 362 Fed. App'x 577 (9th Cir. 2009).

IV. An Injunction Is in the Public Interest

Hologenix argues that an injunction is not in the public interest, citing First Amendment commercial speech decisions of the Supreme Court. But the Supreme Court's framework for analyzing commercial speech under the First Amendment is not a four-factor test with each factor given equal weight. Rather, it is a "four-part analysis" that must be conducted in order. As the Court wrote:

> ***At the outset***, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and ***not be misleading***. Next, we ask whether the asserted governmental interest is substantial. ***If both inquiries yield positive answers***, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980) (emphasis added).

Whether the commercial speech being regulated is "not misleading" is the ***threshold question*** regarding regulation of commercial speech. Commercial speech that is misleading is simply not analyzed under the *Hudson Gas* test. The Supreme Court has long held that "[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake." *Virginia State Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

Nor does corrective advertising violate the public interest. Corrective advertising is not "unprecedented," as Hologenix argues, but has been a staple of Lanham Act cases for decades. (ECF 32 at 29). The First Amendment concerns

regarding corrective advertising were litigated to the DC Circuit in 1977, which held that without corrective advertising, consumers would "continue to buy the product on the strength of the impression built up by prior advertising," which, since that prior advertising was false, "would be unfair and deceptive." *Warner-Lambert Co. v. F.T.C.*, 562 F.2d 749, 761 (D.C. Cir. 1977). Drawing on Supreme Court precedent that the First Amendment provides "no obstacle" to remedying commercial speech that "is not provably false, or even wholly false, but only deceptive or misleading," the *Warner-Lambert* court endorsed corrective advertising as a remedy for false statements, citing V*irginia State Bd. of Pharmacy*, 425 U.S. 748 at 771.

Since *Warner-Lambert*, corrective advertising has become a regular fixture in Lanham Act cases, even at the preliminary injunction stage. It has been endorsed as a "less severe remed[y]," and one that would "serve, rather than disserve, the public interest in truthful advertising." *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 18–19 (7th Cir. 1992). When a campaign is deceptive, corrective advertising may be issued to correct "the misleading nature of that campaign." *N. Star Indus., Inc. v. Douglas Dynamics LLC*, 848 F. Supp. 2d 934, 951 (E.D. Wis. 2012). The Ninth Circuit recently held that a city ordinance that penalizes false advertisers by requiring corrective advertising does not violate the First Amendment because it "only regulates false or misleading commercial speech." *First Resort, Inc. v. Herrera*, 860 F.3d 1263, 1271 (9th Cir. 2017), *cert. denied*, 138 S. Ct. 2709 (2018).

The injunction will serve "the most basic public interest at stake in all Lanham Act cases [which is] the interest in prevention of confusion, particularly as it affects the public interest in truth and accuracy." *Warner Bros. Entm't vs. Glob. Asylum, Inc.*, 2012 WL 6951315 (C.D. Cal. Dec. 10, 2012), *aff'd sub nom. Warner Bros. Entm't v. Glob. Asylum, Inc.*, 544 Fed. App'x 683 (9th Cir. 2013).

V. Hologenix's Unclean Hands Defense is Meritless

To succeed in an unclean hands defense in Lanham Act cases, "the defendant

must demonstrate that the plaintiff's conduct is inequitable and that the conduct ***relates to the subject matter of its claims***." *Fuddruckers, Inc. v. Doc's B.R. Others, Inc.*, 826 F.2d 837, 847 (9th Cir. 1987) (emphasis added). *See also Ellenburg v. Brockway, Inc.*, 763 F.2d 1091, 1097 (9th Cir. 1985) (plaintiffs hands must be clean "as to the controversy in issue"). Hologenix objects to certain claims that MET makes on its websites, and alleges that MET "did not obtain approval from the FDA to make these statements." (Opp. at 21). But the statements MET makes on its own site do not relate to the subject matter of MET's claims against Hologenix; more to the point, MET's statements are entirely appropriate and substantiated.

MET does not seek an injunction based on statements Hologenix has made for which it needed FDA's permission. It seeks one based upon what Hologenix has said ***about the purported FDA "approval" and "determination."*** MET never claimed that the FDA approved its product and never stated that the FDA endorsed its underlying claims. The claims MET makes about its products are supported by clinical studies, including studies on human subjects. (Supp. Vissman Decl. ¶ 4). Moreover, read in context, MET's statements are general wellness statements, and do not need to be reviewed by the FDA. (Supp. Gutierrez Decl. ¶¶ 14–17).

Hologenix's unclean hands defense only shows why it has violated the Lanham Act. Hologenix does not distinguish between making a claim about a product (*e.g.*, that bioceramics can help healthy athletes recover after exercise) and making a claim about what the FDA has "approved" or "determined."

CONCLUSION

MET respectfully requests that this Court grant its motion and issue the proposed injunction.

Dated: May 20, 2019

Respectfully submitted,

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